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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/737,318	12/15/2003	David W. Morris	CHIR0018-100 (23352.0001)	1869

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EXAMINER	
YAO, LEI	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 09/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/737,318	MORRIS ET AL.	
	Examiner	Art Unit	
	Lei Yao, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-72* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15 and 45-46, drawn to an isolated nucleic acid comprising at least 10 contiguous nucleotides of SEQ ID NOs listed in claim 1, antisense, and microarray, classified in class 536, subclass 23.1 and 24,1

II. Claims 16-21, drawn to an isolated polypeptide, encoded within an open reading frame of a cancer associated sequence listed in tables 1-10, classified in class 530, subclass 300 and 350.

III. Claims 22-41, drawn to an isolated antibody or antigen binding fragment that binds to a polypeptide listed in table 1-18, hybridoma, pharmaceutical composition, classified in class 530, subclass 387.1.

IV. Claims 42, drawn to a method for detecting a presence or an absence of cancer cells in an individual, comprising detecting a complex of a cancer associated protein with an antibody to the polypeptide listed tables 1-10, classified in class 435, subclass 7.1.

V. Claims 43-44, drawn to a method for inhibiting growth of cancer cells in an individual and , comprising administering and delivering to the individual an effective amount of a pharmaceutical composition containing antibody to an polypeptide listed tables 1-10, classified in class 424, subclass 184.1.

VI. Claims 47-48, drawn to an electronic library comprising a polynucleotide comprising polynucleotide sequence selected from, classified in class 536, subclass 23.1.

VII. Claim 49, drawn to an electronic library comprising a polypeptide, or fragments, classified in class 530, subclass 300 and 350.

VIII. Claims 50-53, drawn to a method of screening an anticancer drug and comparing the level of expression of the cancer associated gene encoded by a nucleic acid sequence listed in tables 1-10, classified in class 435, subclass 6.

IX. Claims 54-55, drawn to a method of screening a anticancer drug and comparing the level of the cancer associated polypeptide listed in tables 1-10, classified in class 435 subclass 4.

X. Claims 56, drawn to a method of detecting cancer associated with the presence of an antibody in a test serum sample, wherein the antibody against an antigenic polypeptide listed in tables 1-10, classified in class 435, subclass 7.1.

XI. Claims 57-60, drawn to a method of screening for a bioactive agent capable of modulating an activity of a cancer associated protein, sequence listed in tables 1-10, classified in class 435, subclass 4 and 7.

XII. Claim 61, drawn to a method of diagnosing cancer comprising determining the expression of a gene listed in tables 1-10, classified in class 435, subclass 6.

XIII. Claims 63, drawn to a method of treating cancer comprising administering to a patient an inhibitor of cancer associated protien, which is bind to cancer associated protein, listed in tables 1-10, classified in class 424, subclass 277.1 and 184.1.

XIV. Claim 64, drawn to a method of treating cancer comprising administering to a patient an inhibitor of cancer associated protein, wherein the inhibitor is a signaling protein antagonist, listed in tables 1-10, classified in class 514, subclass 2 and classified in class 424, subclass 277.1 and 184.1.

XV. Claim 65, drawn to a method of treating cancer comprising administering to a patient an inhibitor of cancer associated protein, wherein the inhibitor is a cell adhesion protein antagonist, listed in tables 1-10, classified in class 424, subclass 277.1.

XVI. Claim 66, drawn to a method of treating cancer comprising administering to a patient an inhibitor of cancer associated protein, wherein the inhibitor is a serine protease inhibitor antagonist, listed in tables 1-10, classified in class 424, subclass 277.1.

XVII. Claim 67, drawn to a method of treating cancer comprising administering to a patient an inhibitor of cancer associated protein, wherein the inhibitor is nucleic acid binding protein, listed in tables 1-10, classified in class 424, subclass 277.1 and 94.1.

XVIII. Claim 68, drawn to a method of treating cancer comprising administering to a patient an inhibitor of cancer associated protein, wherein the inhibitor is an ion transport protein listed in tables 1-10, classified in class 424, subclass 277.1.

XIX. Claim 69, drawn to a method of treating cancer comprising administering to a patient an inhibitor of cancer associated protein, wherein the inhibitor is a histocompatility antigen antagonist,, listed in tables 1-10, classified in class 424, subclass 277.1 and class 514, subclass 2.

XX. Claim 70-72, drawn to a method of inhibiting expression of a cancer associated gene in a cell by short interfering RNA (siRNA), classified in class 514, subclass 44.

Claim 62 link(s) inventions XIV-XX. The restriction requirement between /among the linked inventions is subject to the nonallowance of the linking claim(s), claim 62 Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to exami-nation in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutorydouble patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions are distinct each from the other because of the following reasons:

The polypeptide of group II and polynucleotide of group I are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In

the present claims, a polynucleotide of group I does not necessarily encode a polypeptide of group II. Similarly, the nucleic acid molecule is complementary to the coding sequence, and therefore would not encode the polypeptide of group II. Furthermore, the information provided by the polynucleotide of group I can be used to make a materially different polypeptide than that of group II. In addition, while a polypeptide of group II can made by methods using some, but not all, of the polynucleotides that fall within the scope of group I, it can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of groups I and II are patentably distinct.

The polypeptide of Group II and the antibody of Group III are patentably distinct for the following reasons. While the inventions of both Group II and Group III are polypeptides, in this instance the polypeptide of Group II is a single chain molecule, whereas the polypeptide of Group III encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions. Thus the polypeptide of Group II and the antibody of Group III are structurally distinct molecules; any relationship between a polypeptide of Group II and an antibody of Group III is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide. Furthermore, searching the inventions of Group II and Group III would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of Group III. Furthermore, antibodies which bind to an epitope of a polypeptide of Group II may be known even if a polypeptide of Group II is novel. In addition, the technical literature search for the polypeptide of Group II and the antibody of Group III are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

The polynucleotide of group I and the antibody of group III are patentably distinct for the following reasons. The antibody of group III which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group I will not encode an antibody of group III, and the antibody of group III cannot be encoded by a polynucleotide of group I. Therefore the antibody and polynucleotide are patentably distinct.

Inventions III and IV/V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used to treat other diseases other than inhibition cancer cell growth or detecting cancer.

Inventions I-III, VI-VII are patentably distinct products.

Invention VIII-XX are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions VIII-XX are unrelated because each invention required different treating materials and have different modes of operation. Therefore, each invention may need different patient populations or biological samples from different patients.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, Therefore, restriction for examination purposes as indicated is proper.

Searching the inventions of groups together would impose a serious search burden. The search required for one group is not required for the other groups because each group requires a different non-

patent literature search due to each group comprising different products and/or method steps, Therefore, restriction for examination purposes as indicated is proper.

Furthermore, if applicants elect any one of the groups set forth above, further restriction is required under 35 U.S.C. 121:

A. Elect **one single gene or one single polypeptide** from tables 1-18

If applicants elect invention XI, additional restriction is required under 35 U.S.C. 121:

B. Elect **one activity listed** in table 12 (note: not one gene or SEQ ID NO).

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOs is a unique and separately patentable sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would constitute an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

In order to be fully responsive, Applicant must elect one from Groups I-XX, one from Group A and/or B even though the requirement is traversed. Applicant is advised that neither I-XX nor A-B is species election requirements; rather, each of I-XX and A-B is a restriction requirement.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitation of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. 821.04. Process claims that depend from or otherwise include all the limitation of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. thus, to be allowable, the rejoined claims must meet the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected

product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that process claims should be amended during prosecution either to maintain dependency on the product claims or otherwise include the limitation of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-4.30pm Monday to Friday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Ph.D.
Examiner
Art Unit 1642

LY

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
9/13/05